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NEW YORK, NY 100368403

EXAMINER

BROWE, DAVID

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1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,097	Applicant(s) SCHUSTER ET AL.	
	Examiner DAVID M. BROWE	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>February 18, 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-12 are pending.

Applicants timely submission of amendments and arguments on February 18, 2010 in response to the First Office Action on the Merits is hereby acknowledged.

Priority

Applicant's claim for the benefit of prior-filed International Application No. PCT/EP2005/002615, filed March 11, 2005 under 35 U.S.C. 365(c), is acknowledged. Acknowledgment is also made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been received for parent Application No. 10 2004 014 020.0, filed in the Federal Republic of Germany on March 19, 2004.

Applicants rights to the said domestic and foreign priority benefits are hereby re-confirmed as previously acknowledged in a telephone interview with Mr. Mark A. Farley, Attorney at Ostrolenk Faber, LLP in New York, New York, on December 7, 2009; any statement(s) in the First Office Action to the contrary notwithstanding.

Withdrawal of Prior Claim Rejections - 35 USC § 112 2nd Paragraph

Claims 2, 3, and 8 have been satisfactorily amended to remove indefinite terms. Therefore, the 35 USC § 112 2nd Paragraph rejection of claims 2-3 and 8-12 presented in the First Office Action is hereby withdrawn.

Withdrawal of Prior Claim Rejections - 35 USC § 102 and 103

Neither Vatter *et al.* nor Schmidt *et al.* explicitly disclose isolating the titanium dioxide pigment particles with at least one silicon dioxide coating to attenuate titanium dioxide's interaction with and breakdown of UV absorbers, as stipulated in the newly

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amended claims. Therefore, the 35 USC § 102 rejection of claim 1 and the 35 USC § 103 rejection of claims 1-12 presented in the First Office Action are hereby withdrawn.

However, a new grounds of rejection is being made herein below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for “at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment to **greatly decrease** breakdown of the UV absorbers”, does not reasonably provide enablement for “at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment to **prevent** breakdown of the UV absorbers”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

Let the Examiner be clear: Applicant is not enabled for prevention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of

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ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation. While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that a cream composition containing pearlescent effect pigments coated with silicon dioxide shows a greatly decreased amount of avobenzone degradation upon sunlight exposure compared to an identical cream subjected to the same conditions, but wherein the pearlescent effect pigments are not coated with silicon dioxide. However, applicants are purporting that coating titanium dioxide pigments with silicon dioxide completely and absolutely prevents breakdown of UV absorbers in a UV-protective cosmetic composition under any and all conditions.

2) Nature of the invention

The nature of the invention is directed to a stable UV-protective cosmetic composition comprising one or more UV absorbers and titanium dioxide-containing effect pigments. Since the Patent Office interprets the term "prevent" as an absolute that has to happen 100% of the time all the time, the invention is directed to UV protective

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cosmetic compositions comprising one or more UV absorbers and titanium dioxide-containing effect pigments, wherein the UV absorbers are completely, absolutely, and eternally stable.

3) Relative level of skill possessed by one of ordinary skill in the art

MPEP 2141.03 states (in part), "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 167 LEd2d 705, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. At 1396, 82 USPQ2d at 1396. The "hypothetical person having ordinary skill in the art" to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." Ex parte Hiyamizu, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.).

4) State of, or the amount of knowledge in, the prior art

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Schumacher *et al.* (U.S. Patent Application No. 2003/0104198) disclose that titanium dioxide; widely used as effect pigments in sunscreen agents based on its ability to reflect, scatter, and absorb harmful UV radiation; exerts an undesirable photocatalytic breakdown of UV absorbers when these agents coexist in a sunscreen formulation, and that surrounding titanium dioxide with a protective coating can significantly attenuate this problem to a low level (Pg. 1, secs. 0004-0008, 0020). Furthermore, UV absorbing agents are susceptible to breakdown from other sources; for example, cinnamic esters are susceptible to alkaline hydrolysis independent of titanium dioxide (Radhakrishnamurti).

5) Level or degree of predictability, or a lack thereof, in the art

There is a high degree of unpredictability regarding the complete, absolute, and eternal stability of UV absorbing agents. UV absorbing agents are susceptible to both titanium dioxide dependent and independent sources of breakdown; and, as disclosed by Schumacher *et al.*, even surrounding and isolating titanium dioxide with a coating of silicon dioxide cannot completely and absolutely prevent the breakdown of UV absorbing agents.

6) Amount of guidance or direction provided by the inventor

Applicant is required to provide in the specification additional guidance and direction with respect to how to make and use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses that "*It has been found, surprisingly, that effect pigments, in particular pearlescent pigments, can be stabilized by the application*

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of at least one protective coating such that no, or only an insignificant, degradation of functional organic constituents, such as UV absorbers, takes place in a cosmetic preparation subjected to sunlight radiation” (Pg. 4), it remains silent on how to practically make and use stabilized effect pigments by the application of at least one protective coating such that no degradation of functional organic constituents, such as UV absorbers, ever takes place in a cosmetic preparation subjected to sunlight radiation.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to the complete, absolute, and eternal prevention of breakdown of UV absorbers.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising finding the ideal coating dimensions and characteristics and testing its ability to completely and absolutely prevent breakdown of UV absorbers from any and all potential sources, including breakdown independent of titanium dioxide's photocatalytic action, in a UV-protective cosmetic composition over time. Essentially, one of ordinary skill in the art has to figure out how to do this themselves. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation.

Genetech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” (Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher *et al.* (U.S. Patent Application No. 2003/0104198).

Schumacher *et al.* disclose a UV-protective cosmetic preparation comprising one or more UV absorbers and effect pigments, wherein the effect pigments contain titanium dioxide and at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment to prevent breakdown of the UV absorbers (Pg. 1, secs. 0002, 0004-0007, 0008, 0010, 0020; Pg. 2, secs. 0022, 0024-0026, 0028-0031; Pg. 3, sec. 0041, 0043, 0045-0047). The effect pigments are pearlescent pigments, have a layer-on-substrate build-up, and a transparent protective coating (Pg. 1, secs. 0010, 0016, 0020; Pg. 2, secs. 0024-0026). The cosmetic preparation is a sunscreen agent in the form selected from the group consisting of a cream, lotion, milk, emulsion, spray emulsion, jelly, oil, spray oil, and an aerosol (Pg. 3, secs. 0041, 0043, 0045-0047). The

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UV absorber is an organic UV absorber selected from the group consisting of benzophenones, hydroxynaphthoquinones, phenylbenzoxazoles, phenylbenzimidazoles, digalloyl trioleate, aminobenzoic acid esters, salicylic acid esters, acyclic dienones, cinnamic esters, benzalazine, avobenzene, paraaminobenzoic acid and derivatives thereof, cinnamates, salicylates, camphor derivatives, benzimidazoles, 4-isopropylidibenzoylmethane, 4-(1,1-dimethylethyl)-4'-methoxydibenzoylmethane, 2,4-dimethyl-4'-methoxydibenzoylmethane and mixtures thereof (Pg. 3, secs. 0041, 0043, 0046).

Schumacher *et al.* also disclose a method for the production of a UV-protective cosmetic preparation comprising providing in said preparation at least one effect pigment, wherein the effect pigments contain titanium dioxide and at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment. The effect pigments are pearlescent pigments, have a layer-on-substrate build-up, and a transparent protective coating. The cosmetic preparation is a sunscreen agent (Pg. 1, secs. 0002, 0004-0007, 0008, 0010, 0020; Pg. 2, secs. 0022, 0024-0026, 0028-0031; Pg. 3, sec. 0041, 0043, 0045-0047).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vatter *et al.* (U.S. Patent Application Pub. No. 2002/0018790).

Applicant Claims

Applicants claim a UV-protective cosmetic preparation comprising one or more UV absorbers and effect pigments, wherein the effect pigments contain titanium dioxide and at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment to prevent breakdown of the UV absorbers. The effect pigments are pearlescent pigments, have a layer-on-substrate build-up, and a transparent protective

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coating. The cosmetic preparation is a sunscreen agent in the form selected from the group consisting of a cream, lotion, milk, emulsion, spray emulsion, jelly, oil, spray oil, and an aerosol. The UV absorber is an organic UV absorber selected from the group consisting of benzophenones, hydroxynaphthoquinones, phenylbenzoxazoles, phenylbenzimidazoles, digalloyl trioleate, aminobenzoic acid esters, salicylic acid esters, acyclic dienones, cinnamic esters, benzalazine, avobenzene, paraaminobenzoic acid and derivatives thereof, cinnamates, salicylates, camphor derivatives, benzimidazoles, 4-isopropylidibenzoylmethane, 4-(1,1-dimethylethyl)-4'-methoxydibenzoylmethane, 2,4-dimethyl-4'-methoxydibenzoylmethane and mixtures thereof.

Applicants also claim a method for the production of a UV-protective cosmetic preparation comprising providing in said preparation at least one effect pigment, wherein the effect pigments contain titanium dioxide and at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment. The effect pigments are pearlescent pigments, have a layer-on-substrate build-up, and a transparent protective coating. The cosmetic preparation is a sunscreen agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Vatter *et al.* disclose a UV-protective cosmetic preparation comprising one or more UV absorbers; and multi-layer, pearlescent effect pigments containing titanium dioxide and at least one protective coating isolating the titanium dioxide from its environment (Pg. 1, secs. 0012-0018; Pg. 2, sec. 0034; Pg. 6, secs. 0086-0088; Pg. 7, sec. 0090; Pg. 12, secs. 0178-0183; Pg. 13, secs. 0186-0188; Pg. 14, sec. 0199). The

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at least one titanium dioxide pigment protective coating is silicon dioxide, which is inherently transparent. The cosmetic preparation is a sunscreen agent that can contain an organic UV absorber selected from the group consisting of benzophenones, hydroxynaphthoquinones, phenylbenzoxazoles, phenylbenzimidazoles, digalloyl trioleate, aminobenzoic acid esters, salicylic acid esters, acyclic dienones, cinammic esters, benzalazine, avobenzene, paraaminobenzoic acid and derivatives thereof, cinnamates, salicylates, camphor derivatives, benzimidazoles, 4-isopropylidibenzoylmethane, 4-(1,1-dimethylethyl)-4'-methoxydibenzoylmethane, 2,4-dimethyl-4'-methoxydibenzoylmethane and mixtures thereof; and exists in a form selected from the group consisting of a cream, lotion, milk, emulsion, spray emulsion, jelly, oil, spray oil, and aerosol (Pg. 2, sec. 0034; Pg. 12, secs. 0179-0183; Pg. 15, sec. 0210; Pg. 16, sec. 0216).

Vatter *et al.* also disclose a method for the production of a UV-protective cosmetic preparation comprising providing in said preparation at least one effect pigment, wherein the effect pigments contain titanium dioxide and at least one protective coating of silicon dioxide isolating the titanium dioxide from its environment. The effect pigments are pearlescent pigments, have a layer-on-substrate build-up, and a transparent protective coating. The cosmetic preparation is a sunscreen agent.

Ascertainment of the Difference Between the Scope of the Prior Art and the Claims (MPEP §2141.012)

Vatter *et al.* disclose a UV-protective cosmetic sunscreen composition comprising an organic UV absorber and at least one effect pigment, wherein the effect

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pigment(s) contain titanium dioxide and at least one protective coating isolating the titanium dioxide from its environment; and that the protective coating can be chosen from a generic list of organic and inorganic agents including silicon dioxide. Vatter *et al.*, however, do not explicitly disclose the particular choice of a silicon dioxide coating that isolates the titanium dioxide from its environment to prevent its interaction with and breakdown of UV absorbers. However, the disclosure is sufficient to render the claims obvious under 35 USC § 103.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of the present invention to employ the teachings of Vatter *et al.* to devise applicants claimed invention. Schumacher *et al.* disclose that a problem widely recognized among those of ordinary skill in the art is the ability of titanium dioxide to exert an undesirable photocatalytic breakdown of UV absorbers when these agents coexist in a sunscreen formulation, and that surrounding titanium dioxide with a protective coating can significantly attenuate this problem. Since Vatter *et al.* disclose that titanium dioxide effect pigments can be coated to isolate the titanium dioxide from its environment in sunscreen agent containing UV absorbers, and that this coating can be silicon dioxide, one of ordinary skill in the art would be motivated to design the titanium dioxide pigments to include at least one silicon dioxide coating, with the reasonable expectation that the said coating will successfully attenuate titanium dioxide's undesirable photocatalytic breakdown of the UV absorbers.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID M. BROWE whose telephone number is 571-270-1320. The examiner can normally be reached on Monday-Friday 7:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID M. BROWE
Patent Examiner, Art Unit 1616

/Ernst V Arnold/
Primary Examiner, Art Unit 1616